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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/214,723	01/11/99	OKA	171-613P

HM22/1018  
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EXAMINER	
PAWUL, A	
ART UNIT	PAPER NUMBER
1653	

**DATE MAILED:** 10/18/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/214,723

Applicant(s)

Takanori Oka

Examiner

Anna Pawul

Group Art Unit

1653



☒ Responsive to communication(s) filed on Jan 11, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-10 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-10 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 2 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what applicant means by "A/B" and "B/A" in the claim. This renders the claim indefinite. Please clarify.

3. The term "utilizing theoretical values" in claim 3 is a relative term which renders the claim indefinite. The term "utilizing theoretical values" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what standard is being referred to by the applicant. Please clarify.

4. The term "labeled standard DNA" in claims 1- 3, 7- 9, is a relative term which renders the claim indefinite. The term "labeled standard DNA" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is

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unclear what constitutes "labeled standard DNA". Please define what is meant in this particular circumstance.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 4-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al (US Patent 5,500,356), de la Chapelle et al (US Patent 5,492,808) and Carson et al (US Patent 5,747,251).

Li et al teach an nucleic acid assay process that includes amplifying a particular region of a nucleic acid, hybridization of the nucleic acid to a probe that is bound to a solid support and is labeled, as well as the use of primers (col 3-4, lines 44-67 & 1-40, claim 1).

De la Chapelle et al teach the use of a nucleic acid assay where the sample DNA is one that is a cancer-related gene. They also teach amplification of the sample DNA, the use of primers, the use of a labeled hybridization nucleic acid that can be connected to a solid support and the use of a kit (abstract, claims 10, 11).

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Carson et al teach the use of competitive PCR and the applications of this assay in the diagnosis of diseases such as cancer, HIV and other genetic disease ( col. 8, lines 22-31). They also teach the use of probes, amplification of target DNA and labeled detection of the product and the use of a solid support (claims).

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Li et al (US Patent 5,500,356), de la Chapelle et al (US 5,492,808) and Carson et al (US 5,747,251). One of ordinary skill in the art would have been motivated to use a nucleic acid assay where the sample is taken from a cancer gene or a gene related to a genetic disease.

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Pawul whose telephone number is (703) 305-0806. The examiner can normally be reached Monday-Friday 7:30 AM to 4:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be normally reached on Monday-Thursday from 8:00 AM to 5:00 PM (EST) and whose telephone number is (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be

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faxed to group 180 via the PTO Fax Center located in Crystal Mall 1. Papers may be submitted Monday-Friday between 8:00 AM and 4:00 PM (EST). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 fax Center number is (703) 305-3014 or (703) 308-4242.

AP 10-12-99

Eggerton A. Campbell

EGGERTON A. CAMPBELL  
PRIMARY EXAMINER